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| 09/740,679 | 12/19/2000 | J. Stuart Cumming | 13533.4033 | 6074 |
| 34313 7590 07/19/2007 ORRICK, HERRINGTON & SUTCLIFFE, LLP IP PROSECUTION DEPARTMENT 4 PARK PLAZA SUITE 1600 IRVINE, CA 92614-2558 | | | EXAMINER PREBILIC, PAUL B | |
| | | | ART UNIT 3738 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/740,679

Applicant(s)

CUMMING, J. STUART

Examiner

Paul B. Prebilit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-102 and 104-124 is/are pending in the application.
- 4a) Of the above claim(s) 58, 60, 62, 64-71, 75, 78, 79, 81-84, 87-89, 92 and 96-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-57, 59, 61, 63, 72-74, 76, 77, 80, 85, 86, 90, 91, 93-95, 99-102 and 104-124 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 58, 60, 62, 64-71, 75, 76, 78, 79, 81-84, 87-89, 92, and 96-98 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 11, 2002. Claim 65 is dependent upon a withdrawn base claim so it is withdrawn even though the Applicant argued that it was drawn to the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 80, 85, and 86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new subject matter of "a biconvex optic having symmetrical front and back surfaces" does not have original support. It is not clear what these surfaces are symmetrical to. The Examiner has reviewed the specification and could not find support for this limitation and notes that symmetry can be along the optical axis or plane and is not necessarily transverse to the optical axis. Although the drawings can be utilized for what they fairly show, it is not clearly inherent that the lenses of Figures 1 to 8 (upon which Figure 18 is based) are not

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clearly symmetrical since these figures are not drawn to scale. Even if the figures were drawn to scale, it is not clear that the front and back surfaces are symmetrical.

Claims 53-57, 59, 61, 63, 72-74, 77, 90, 91, 93-95, 99-102, and 104-124 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter of "front and back radii being essentially the same" lacks original support and constitutes new matter because continuing prosecution under 37 CFR 1.114 does not allow the introduction of new matter even if filed at the date of the RCE. The Examiner has reviewed the specification and could not find support for this limitation and notes that symmetry can be along the optical axis or plane and is not necessarily transverse to the optical axis. Although the drawings can be relied upon for what they fairly disclose, the Examiner asserts that they do not fairly disclose radii that are essentially the same as claimed. This is due to the fact that they are not drawn to scale and due to the fact that "essentially the same" suggests a close almost identical curvature.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 80, 85, and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention. It is unclear what the front and back surfaces are symmetrical relative to so it is unclear how to interpret the scopes of these claims.

Specification

As an alternative to the rejection of the previous paragraph and to address the situation that there is some inherent or implicit support for symmetrical front and back surfaces, the Examiner objects to the specification as at least failing to give proper antecedent basis to the claimed invention. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

As an alternative to the new matter disclosure pertaining to the radii being “essentially the same”, the Examiner contends that even if this feature were determined to be inherent, this subject matter would still lack antecedent basis from the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 53-57, 59, 61, 63, 72-74, 77, 90, 91, 93-95, 99, 100, 102, and 105-124 are rejected under 35 U.S.C. 102(b) as anticipated by Schlegal (US 4,454,597) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schlegal (US 4,424,597) in view of Tennant (US 4,254,510) or Tennant (US 4,254,509) and further view of Liebermann (US 5,512,039) or Wiley (US 5,066,301). Schlegal anticipates the claim language where the lens and haptic structure is made entirely out of flexible silicone and it is inherently capable of accommodating due to flexing at the haptics to the extent required by the claim language; see Figures 3 and 4 as well as column 3, lines 17-30 and column 4, line 24 to column 5, line 17. The fact that stiffeners can or may be added to increase rigidity indicates that the haptics are inherently quite flexible without this optional feature. Furthermore, the holes are added to the haptics to make them even more flexible as desired; see column 4, lines 38-45. The Examiner considers one haptic being the section or area of the haptic ring between the holes (15). Furthermore, Schlegal discloses that the biconvex lenses can have front surface to back surface radius ratios of between 1.5 to 3.0 (see claims 10 and 11 thereof). The Examiner asserts that a radius that is 1.5 times greater than another radius is "essentially the same" to the extent that this language can be given patentable weight.

Alternatively, one may not consider the claim language "radii essentially the same" as met by Schlegal because one could consider it outside the suggested scope. However, Liebermann (see column 1, lines 6-14) and Wiley (see column 1, lines 9-16) both teach that the natural lens of the eye is essentially symmetrically biconvex when comparing the front and back surfaces. Therefore, it is the Examiner's position that it

would have been at least obvious to make the Schlegel radius ratio closer to 1.0 in order to imitate the shape of the natural lens such that as many variable in lens design can be eliminated as possible.

Additionally, one may not understand Schlegel in the manner the Examiner has interpreted it with respect to multiple haptics being disclosed. However, even if one does not interpret Schlegel as disclosing multiple haptics, Tennant ('509) and Tennant ('510) both teach that it was known to make plate haptics that only partially surround the optic; see the figures of each. For this reason, it would have been obvious to make the Schlegel invention the same way for the same reasons that Tennant ('509) or Tennant ('510) does the same or in order to save on material costs of making the lenses by reducing the lateral width of Schlegel's haptics.

With regard to claim 90, the discrete groove as claimed is met by the ring (12) that is a groove between the lens body (11) and the outer part of the haptic (ridge 17).

With regard to claim 100, the knob as claimed is the ridge (17) of Schlegel.

With regard to claim 123, the groove as claimed is between the lens (11) and the ridge (23).

Claims 80, 85, and 86 are rejected under 35 U.S.C. 103(a) as obvious over Schlegel (US 4,424,597) in view of Tennant (US 4,254,510) or Tennant (US 4,254,509) and further view of Liebermann (US 5,512,039) or Wiley (US 5,066,301). Schlegel meets the claim language where the lens and haptic structure is made entirely out of flexible silicone and it is inherently capable of accommodating due to flexing at the haptics to the extent required by the claim language; see Figures 3 and 4 as well as

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column 3, lines 17-30 and column 4, line 24 to column 5, line 17. The fact that stiffeners can or may be added to increase rigidity indicates that the haptics are inherently quite flexible without this optional feature. Furthermore, the holes are added to the haptics to make them even more flexible as desired; see column 4, lines 38-45. The Examiner considers one haptic being the section or area of the haptic ring between the holes (15). Furthermore, Schlegal discloses that the biconvex lenses can have front surface to back surface radius ratios of between 1.5 to 3.0 (see claims 10 and 11 thereof) but not a ratio of 1.0 as required by the language "symmetrical front and back surfaces.

However, Liebermann (see column 1, lines 6-14) and Wiley (see column 1, lines 9-16) both teach that the natural lens of the eye is essentially symmetrically biconvex when comparing the front and back surfaces. Therefore, it is the Examiner's position that it would have been obvious to make the Schlegal radius ratio closer to 1.0 in order to imitate the shape of the natural lens such that as many variables in lens design can be eliminated as possible.

Additionally, one may not understand Schlegal in the manner the Examiner has interpreted it with respect to multiple haptics being disclosed. However, even if one does not interpret Schlegal as disclosing multiple haptics, Tennant ('509) and Tennant ('510) both teach that it was known to make plate haptics that only partially surround the optic; see the figures of each. For this reason, it would have been obvious to make the Schlegal invention the same way for the same reasons that Tennant ('509) or Tennant ('510) does the same or in order to save on material costs of making the lenses by reducing the lateral width of Schlegal's haptics.

Claims 101 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlegel (US 4,424,597), Tenant ('509), Tenant ('510), Liebermann, and Wiley as set forth in the rejection of claims 53-57, 59, 61, 63, 72-74, 77, 90, 91, 93-95, 99, 100, 102, and 104-124 in further view of a teaching found in Tennant (US 4,254,510). Schlegel fails to disclose pairs of knobs for each haptic as claimed. However, Tennant ('510; see Figure 1 and elements 13a and 14a) teaches that pairs of knobs for each haptic were known. Therefore, it is the Examiner's position that it would have been obvious to form such features on the Schlegel device for stability of the implanted device and for the same reasons that Tennant ('510) utilizes the same.

Response to Arguments

In response to the traversal of Schlegel that it is not clearly an accommodating lens, the Examiner asserts that it is inherently accommodating for the reasons explained in the rejection; see MPEP 2112 that is incorporated herein by reference.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
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